Translation from the Czech language
Authorisation No.: 544/2024/RDI

DECISION on the distribution authorisation

The Institute for State Control of Veterinary Biologicals and Medicines based in Brno (hereinafter referred to as ÚSKVBL) as the competent administrative authority pursuant to Article 100 of Regulation (EU) 2019/6 of the European Parliament and of the Council on Veterinary Medicinal Products (hereinafter referred to as the Regulation), Section 16(2)(a)(2) of Act No. 378/2007 Coll, on Medicines and on Amendments to Certain Related Acts (hereinafter referred to as Act No. 378/2007 Coll., on Medicines) **issues,** pursuant to Article 99 and 100 of the Regulation, Section 76 of Act No. 378/2007 Coll., on Medicines, the following

AUTHORISATION

for the wholesale distribution of veterinary medicinal products

to the following extent and under the following conditions:

1. Operator: **Olikla s.r.o.**
ID NO.: 281 77 738

2. Headquarters of the operator**:**

náměstí Smiřických 42, 281 63 Kostelec nad Černými Lesy

3. The distribution authorisation is granted for the premises and equipment used by the company on the day of the inspection at:

Pražská 390, 285 06 Sázava

4. A qualified person pursuant to Article 101(3) of the Regulation, Section 76(1)(b) of Act No. 378/2007 Coll., on Medicines is:

Mgr. Alice Krejcárková Poláková

5. Scope of authorised activity in the distribution of veterinary medicines:

Distribution of veterinary medicinal products within the meaning of the Regulation, Act No. 378/2007 Coll., on Medicines in the scope of:

- **veterinary medicinal products – other than those requiring handling at low temperatures**
- **cold chain veterinary medicinal products (requiring handling at low temperatures)**

6. The Distributor is obliged to comply with the relevant provisions of the Regulation and the Commission Implementing Regulation (EU) 2021/1248 on measures for good distribution practice of veterinary medicinal products, Act No. 378/2007 Coll., on Medicines and Decree No. 229/2008 Coll., on the

Manufacture and Distribution of Medicines (hereinafter referred to as the Implementing Decree) and the instructions set by the ÚSKVBL pursuant to Section 77(1)(g) of Act No. 378/2007 Coll., on Medicines.

7. The holder of the authorisation is obliged to enable the ÚSKVBL to carry out official supervision pursuant to Article 123 of the Regulation, Section 16(2)(e) of Act No. 378/2007 Coll., on Medicines and to observe the measures imposed pursuant to Section 16(2)(c)(d) of Act No. 378/2007 Coll., on Medicines.
8. The Authorisation is granted for an indefinite period. It may be suspended or revoked pursuant to Article 100(3) of the Regulation, Section 76(3) of Act No. 378/2007 Coll., on Medicines.
9. The Distributor is only allowed to operate with equipment and on premises approved by the inspection team on the inspection day: 26/03/2024 with continued compliance as described in the D1 questionnaire of 27/02/2024.
10. The distribution of narcotic and psychotropic substances and veterinary medicines containing them requires a special permit from the Ministry of Health of the Czech Republic in accordance with Act No. 167/1998 Coll., on Addictive Substances and on Amendments to Certain Other Acts, as amended.

Grounds:

On the basis of an *application for a distribution authorisation for veterinary medicines* submitted to the ÚSKVBL on 29/02/024, file no. ÚSKVBL/2921/2024/POD, filed pursuant to Article 100 of the Regulation, Section 76(2) of Act No. 378/2007 Coll., on Medicines and the Implementing Decree,

payment of the administrative fee pursuant to Act No. 634/2004 Coll., on Administrative Fees, as amended (Item 99),

reimbursement of expenses pursuant to Section 112 of Act No. 378/2007 Coll., on Medicines of 27/02/2024,

submitted documentation demonstrating compliance with the principles of good distribution practice within the meaning of Regulation and Commission Implementing Regulation (EU) 2021/1248 on measures for good distribution practice for veterinary medicinal products, Act No 378/2007 Coll., on Medicines and the Implementing Decree,

the result of the inspection carried out on 26/03/2024, in accordance with the provisions of the Regulation and the Commission Implementing Regulation (EU) 2021/1248 on measures for good distribution practice of veterinary medicinal products, the Implementing Decree and Act No 378/2007 Coll., on Medicines,

the ÚSKVBL found that the applicant complied with the requirements for distribution set out in the Regulation and Commission Implementing Regulation (EU) 2021/1248 on measures for good distribution practice for veterinary medicinal products, Act No 378/2007 Coll., on Medicines and the Implementing Decree, and issued this distribution authorisation for veterinary medicines.

Advice on Appeal:

This Decision may be appealed within 15 days from the date of delivery of the Decision with the State Veterinary Administration of the Czech Republic, through the ÚSKVBL.

Digitally signed by MVDr. Jiří Bureš
Date: 14/06/2024 12:02:44 +02'00'

In Brno, on: 11 June 2024

MVDr. Jiří Bureš
head of the Service Office

Translator's Affidavit

I swear that I am a court translator of the English language appointed by the Regional Court in Ostrava, the Czech Republic, on 19 July 2019, adjudication file number Spr 2390/2018, and I hereby confirm that the attached English text is a true and complete translation of the Czech original herewith. The serial number of this certified translation in the Translator's Register is 150700/2024.

Ing. Mgr. Pavel Brunda, Ph.D.
Dated 27 June 2024

Ing. Mgr. Pavel Brunda Ph.D.

Digitálně podepsal Ing. Mgr. Pavel Brunda Ph.D.
Datum: 2024.06.27 09:51:32 +02'00'